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ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION N 6804 09/486,977 03/06/2000 MARK HANS EMANUEL 10/20/2004 **EXAMINER** 7590 BUI, VY Q JOEL R. PETROW SMITH & NEPHEW, INC. ART UNIT PAPER NUMBER 1450 BROOKS ROAD MEMPHIS, TN 38116 3731

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
		09/486,977	EMANUEL, MARK	HANS
	Office Action Summary	Examiner	Art Unit	
		Vy Q. Bui	3731	
Period f	The MAILING DATE of this communication apports or Reply	pears on the cover shee	t with the correspondence ad	dress
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status	,			
1)⊠	Responsive to communication(s) filed on 07 M	lay 2004.		
2a)⊠	This action is FINAL . 2b) ☐ This	This action is non-final.		
3)[Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposit	tion of Claims			
4)⊠	☑ Claim(s) <u>20-56</u> is/are pending in the application.			
	4a) Of the above claim(s) 24-37 is/are withdrawn from consideration.			
5)[Claim(s) is/are allowed.			
6)⊠	Claim(s) <u>20-23 and 38-56</u> is/are rejected.			
7)	Claim(s) is/are objected to.			
8)□	Claim(s) are subject to restriction and/or election requirement.			
Applicat	tion Papers			
9)☐ The specification is objected to by the Examiner.				
10)	D) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.			
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority	under 35 U.S.C. § 119			
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachme	nt(s)			
	ce of References Cited (PTO-892)		ew Summary (PTO-413)	
	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)		No(s)/Mail Date of Informal Patent Application (PTC	D-152)
	er No(s)/Mail Date <u>5/7/2004</u> .		See Continuation Sheet.	

Continuation of Attachment(s) 6). Other: one sheet reciting a definition of "endoscope".

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 20-21 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over KAGAWA et al (5,163,433).

As to claims 20-21, KAGAWA discloses an ultrasound cutting device for removal of tissue from a body cavity in a human being (column 1, lines 11-16) including an ultrasonic probe 3 which defines a first suction passage/first path 21 for discharging fluid with detached tissue, an outer tube 22b, an inner tube 22a, fluid pump 42 and suction pump 41. Probe 3 and inner tube 22a define fluid supply passage 25, inner tube 22a and outer tube 22b defines fluid passage 26 for discharging substantially only fluid along a second path because the suction mouth of the discharge passage 26 is next to the supply mouth of the supply passage 25 (see Fig. 1). Inherently, to avoid over flow of the body cavity, the fluid supplied from passage 25 and fluid discharged through passages 21 and 26 must be regulated so as to keep a balance between inflow fluid from passage 25 and outflow fluid through passages 25 and 26. Therefore, the pressure in the cavity body should be substantially constant. Similarly, the KAGAWA device inherently discloses a method of discharging fluid with detached tissue through a first path (passage 21) and discharging substantially only fluid along a second path (passage 26) so as to regulate the pressure in the body cavity to remain substantially constant. Alternately, to avoid

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over flow of fluid from the body cavity, it would have been obvious to one of ordinary skill in the art at the time of the invention to regulate the KAGAWA device a in a method as recited in the claims such that the inflow fluid from passage 25 into the body cavity and the discharge fluid through passages 25, 26 out of the body cavity are maintained substantially the same and such that a pressure in the body cavity is maintained substantially constant as well.

According to the American Heritage Dictionary of the English Language, 3rd edition (please see definition 2 of one-page attachment), "motor is a device that converts any form of energy into mechanical energy". Therefore, KAGAWA device can be considered as **being motor driven** as recited in claim 20 because KAGAWA device is a device that receives electrical energy via piezoelectric elements (10a, 10b) to convert into mechanical energy (ultrasonic vibration of probe 3) by coupling to the other parts of the device (KAGAWA: col.5, lines 21-34).

As to claim 38, KAGAWA discloses the first suction passage/first path 21 for discharging fluid with detached tissue and the fluid passage 26 for discharging substantially only fluid along a second path as mentioned above. First path 21 and second path 26 are different paths and can be considered as separate paths because at least path 21 and 26 are separate in the distal part of the intersection of tube 30 and tube 16. Alternately, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have passage 21 and 26 different and separate along the whole paths as this configuration is just another well known/obvious design choice. Notice that there is no structural limitation in claim 38 to specify if there are different/separate suction pumps for first path and second path or just only one suction pump for both paths. If there is only one vacuum pump in the invention, then first path and second path must have a common portion connecting to the suction pump and the paths are only partially separate. Further to claim 38, notice that passage 21 and 26 are completely separate before connection to branch conduit 16. Alternatively, one can use two separate conduits to connect to path 21 and path 26 without any significant effect on the device performance.

3. Claims 39-42, 44-52 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipate by WALBRINK et al. (US Pat. 5,449,356).

As to claims 39-42, 44-52 and 54-56, WALBRINK (Fig. 1-2, for example) discloses endoscope 20, cutter 120 for cutting a tissue in a body cavity/distensible organ, fluid port 56

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through endoscope 20 for introducing fluid into the organ or for discharging fluid out of the organ, tube 24 for receiving endoscope 20, electrode/cutter 120 for cutting tissue, fluid control device 54 for controlling pressure within the organ, shut-off valve 164. Notice that by definition (see enclosed definition of "endoscope" from "The American Hritage Dictionary of the English Lnaguage, Third Edition, 1922"), it is reasonable to consider device 20 as an endoscope.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over KAGAWA et al (5,163,433).

As to claims 22 and 23, KAGAWA inherently discloses or alternatively suggests a method as recited in the claims, except for using an insertion mandrel for insertion into the body cavity before inserting the device. It is well known in the art to use a mandrel or a trocar to create an access passage to a body cavity before inserting a probe or a cutting device into the body cavity via the access passage. For example, BIRTCHER (WO 93/07821; line 27, page 1 to line 19, page 2) discloses such a standard laparoscopic procedure before inserting a probe or a cutting device into a body cavity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert a mandrel or trocar into a body cavity to create an acces passage and remove the trocar before inserting a probe or cutting device into the body cavity as this is a conventional laparoscopic procedure.

3. Claims 43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over WALBRINK et al. (US Pat. 5,449,356).

As to claims 43 and 52, WALBRINK (col. 8, lines 22-27) discloses a variety of different types of surgical instrument can be used with endoscope 20 through lumen 100. On the other

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hand, a cutter having a channel for discharging fluid and cut tissue is well known. It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert such a cutter through lumen 100 of endosope 20 so as to cut tissue and discharge fluid and tissue through the cutter.

Response to Amendment

The amendment filed on 3/1/2003 under 37 CFR 1.131 has been carefully considered but is most in view of new rejection above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2158. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vy Q. Bui

Primary Examiner
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10/18/204